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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,066	12/03/2003	Athur C. Perry	1987.1-7 (040020)	7966
24243	7590	11/06/2007	EXAMINER	
CHARMASSON, BUCHACA & LEACH, LLP			BLANCO, JAVIER G	
1545 HOTEL CIRCLE SOUTH, SUITE 150			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/728,066	PERRY ET AL.	
	Examiner Javier G. Blanco	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 August 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-10 and 12-30 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                 | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 27, 2007 has been entered.

### ***Response to Amendment***

2. Applicants' amendment of claims 1, 20-22, and 29 in the reply filed on August 27, 2007 is acknowledged.
3. Applicants' addition of claim 30 in the reply filed on August 27, 2007 is acknowledged.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 20 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ragheb et al. (WO 98/36784 A1).

Ragheb et al. disclose a prosthesis (see Figure 6B; see page 27, lines 5-13) comprising a body having a first coating of a first bioactive substance (layer 18) deposited/disposed along an

outer/external first segment (one half of the prosthesis), and a second coating of a different second bioactive substance (layer 18') deposited/disposed along a second outer/external segment (the other half of the prosthesis). The first therapeutic drug/agent could be in the same or different class of therapeutic substance than the second therapeutic drug/agent, therefore the two coatings have different bioabsorbability properties/rates (see pages 12-15; page 24, lines 3-5). Examples of therapeutic drugs/agents are disclosed at pages 12-15. The two coatings are external/exposed to the outer surface of the prosthesis in order to deliver two agents/drugs to the tissue to which the particular surface of the prosthesis is exposed (see page 27, lines 5-13).

**Note:** Regarding the statements of intended use and other functional statements (e.g., “*for implantation into the orbit of a mammal*”; etc.), they do not impose any structural limitations on the claims distinguishable over the device of Ragheb et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

6. Claims 1-10 and 12-30 are rejected under 35 U.S.C. 102(b) as anticipated by Perry (WO 94/14390 A1) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Perry (WO 94/14390

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A1) in view of either Buscemi et al. (US 5,968,092 A), Ragheb et al. (WO 98/36784 A1), or McGhan (US 6,913,626 B2).

Referring to Figures 1, 3, and 4, Perry discloses an orbital implant comprising:

(i) A substantially spheroid body *sized and shaped to be placed* (emphasis added to functional language) in the orbit;

(ii) A coating (“coated” or “wrapped”: see page 5, lines 23-29; page 13, line 34 to page 14, line 2) *sized and shaped to intimately contact* (emphasis added to functional language) a section of said body; and wherein said coating has a first portion having a first bioabsorbability and a second portion having a second bioabsorbability different from said first bioabsorbability. The orbital implant may be coated/impregnated with a first bioabsorbable portion/material (e.g., a vascularization agent) prior to (see page 16, lines 31-35; page 17, lines 4-6) or after (see page 17, lines 7-13) applying a second bioabsorbable portion/material (e.g., collagen, polyglycolic acid, or polylactic acid coating/wrapping), which subject matter is not only well known in the art but is further disclosed at page 22, lines 4-14. The vascularization agent coating/wrapping will have a bioabsorbability rate/property. The biopolymer (e.g., collagen, polyglycolic acid, or polylactic acid) coating/wrapping will have a bioabsorbability rate/property different than the one from the vascularization agent coating/wrapping.

The bioabsorbable (see page 12, lines 5-26) coating/wrapping materials are disclosed as not causing undue adverse immune response (see page 11, lines 19-24). The coating/wrapping may further include therapeutic agents (see page 13, lines 7-8; page 14, lines 14-29), color-coding indicia (see page 22, lines 15-18), passageways *sized to allow* (emphasis added to functional language) fluid exchange therethrough (see page 16, lines 25-29; page 23, lines 34-37;

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page 28, lines 19-23), a surface having microtexturing (see page 14, lines 31-36; page 24, lines 14-15) and/or an outer surface which is smoother than a first surface (see page 12, lines 27-29; page 14, lines 31-36; page 24, lines 15-17), a thickness of less than one millimeter (see page 12, lines 27-29), and a thickness *selected to allow melting penetration* (emphasis added to functional language) using a handheld cautery (see page 29, lines 11-14).

The coatings/wrappings are disclosed as either liquid or as sheet-like biopolymer that may be wrapped around the outer surface of the orbital implant (see Abstract; page 13, line 34 to page 14, line 2; page 22, lines 3-10). The two coatings/wrappings are “separate” since they are not blended/mixed. Chemical and/or molecular bonds keep said first and second portions/materials bonded. Also, the two coatings/wrappings are “separate” since they are coated/wrapped at different time frames.

Regarding the limitation “external and exposed anchoring coating portion”, each of said coatings/wrappings will be covering (directly or indirectly) first and second outer surface sections of the porous core. Therefore, the two coverings are external to the core. Further, when (for example) the first coating is partially degraded it will expose the second coating next to it, or underneath it.

It should be noted implants/prostheses comprising two or more external and exposed coatings are already known in the art:

- a. For example, Buscemi et al. disclose a prosthesis (10) comprising a body (11) having a first non-liquid (e.g., either when the coating is dry, or layer is formed on top of the surface) external and exposed anchoring coating portion (16 and /or 18) having a first bioabsorbability rate, and a second non-liquid (e.g., either when the coating is dry, or layer is formed on top of the

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surface) external and exposed anchoring coating portion (22) having a second bioabsorbability rate different from said first bioabsorbability rate (see column 6, lines 1-41) in order to obtain a prosthesis that will degrade in a predictable fashion (see column 12, lines 6-13). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a prosthesis having external/exposed biodegradable coatings covering first and second outer surfaces of the prosthesis, as taught by Buscemi et al., with the prosthesis of Perry, in order to obtain a prosthesis that will degrade in a predictable fashion.

b. For example, Ragheb et al. disclose a prosthesis (see Figure 6B; see page 27, lines 5-13) having a first coating of a first bioactive substance (layer 18) deposited/disposed along an outer first segment (one half of the prosthesis), and a second coating of a different second bioactive substance (layer 18') deposited/disposed along a second outer segment (the other half of the prosthesis). The first therapeutic drug/agent could be in the same or different class of therapeutic substance than the second therapeutic drug/agent (see pages 12-15; page 24, lines 3-5). Examples of therapeutic drugs/agents are disclosed at pages 12-15. The two coatings are external/exposed to the outer surface of the prosthesis in order to deliver two agents/drugs to the tissue to which the particular surface of the prosthesis is exposed (see page 27, lines 5-13). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a prosthesis having two coatings external/exposed to the outer surface of the prosthesis, as taught by Ragheb et al., with the prosthesis of Perry, in order to deliver two agents/drugs to the tissue to which the particular surface of the prosthesis is exposed.

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c. For example, McGhan discloses a prosthesis (100) comprising a core (11) having first and second external and exposed (see column 7, lines 35-42) anchoring coating portions (41, 101) having different bioabsorbability rates in order to promote tissue integration and anchoring as the coating portions are periodically biodegraded (see column 7, lines 11-50). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a prosthesis having external/exposed biodegradable coatings covering first and second outer surfaces of the prosthesis, as taught by McGhan, with the prosthesis of Perry, in order to promote tissue integration and anchoring as the coating portions are periodically biodegraded.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-4, 7-9, 17, 19-22, 24, 25, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vachet (US 5,089,021 A) in view of Buscemi et al. (US 5,968,092 A), Ragheb et al. (WO 98/36784 A1), or McGhan (US 6,913,626 B2).

Referring to Figures 1, 2, and 6-8, Vachet discloses an orbital implant (1) which comprises a porous core (36); an anterior first non-liquid external and exposed anchoring coating portion (Figures 1 and 2: strip 6; Figures 6-8: strip 16) covering a first outer surface section of said core; and a second non-liquid external and exposed coating portion (Figures 1 and 2: strip 7;

Figures 6-8: strip 17), distinct from said first portion, covering a second outer surface section of said core. Said first and second coating portions are either bonded or sutured to one another along a bond (e.g., edge to edge; see column 3, lines 63-67; column 4, lines 14-23; column 5, lines 7-10).

Although Vachet desirability is to achieve tissue integration of the orbital implant, he did not particularly disclose the first and second coating portions as comprising materials comprising different bioabsorbability rates. However, this is already known in the art.

a. For example, Buscemi et al. disclose a prosthesis (10) comprising a body (11) having a first non-liquid (e.g., either when the coating is dry, or layer is formed on top of the surface) external and exposed anchoring coating portion (16 and /or 18) having a first bioabsorbability rate, and a second non-liquid (e.g., either when the coating is dry, or layer is formed on top of the surface) external and exposed anchoring coating portion (22) having a second bioabsorbability rate different from said first bioabsorbability rate (see column 6, lines 1-41) in order to obtain a prosthesis that will degrade in a predictable fashion (see column 12, lines 6-13). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a prosthesis having external/exposed biodegradable coatings covering first and second outer surfaces of the prosthesis, as taught by Buscemi et al., with the prosthesis of Vachet, in order to obtain a prosthesis that will degrade in a predictable fashion.

b. For example, Ragheb et al. disclose a prosthesis (see Figure 6B; see page 27, lines 5-13) having a first coating of a first bioactive substance (layer 18) deposited/disposed along an outer first segment (one half of the prosthesis), and a second coating of a different second bioactive

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substance (layer 18') deposited/disposed along a second outer segment (the other half of the prosthesis). The first therapeutic drug/agent could be in the same or different class of therapeutic substance than the second therapeutic drug/agent (see pages 12-15; page 24, lines 3-5). Examples of therapeutic drugs/agents are disclosed at pages 12-15. The two coatings are external/exposed to the outer surface of the prosthesis in order to deliver two agents/drugs to the tissue to which the particular surface of the prosthesis is exposed (see page 27, lines 5-13). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a prosthesis having two coatings external/exposed to the outer surface of the prosthesis, as taught by Ragheb et al., with the prosthesis of Vachet, in order to deliver two agents/drugs to the tissue to which the particular surface of the prosthesis is exposed.

c. For example, McGhan discloses a prosthesis (100) comprising a core (11) having first and second external and exposed (see column 7, lines 35-42) anchoring coating portions (41, 101) having different bioabsorbability rates in order to promote tissue integration and anchoring as the coating portions are periodically biodegraded (see column 7, lines 11-50). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a prosthesis having external/exposed biodegradable coatings covering first and second outer surfaces of the prosthesis, as taught by McGhan, with the prosthesis of Vachet, in order to promote tissue integration and anchoring as the coating portions are periodically biodegraded.

***Response to Arguments***

9. With regards to the 103(a) rejection based on Perry (WO 94/14390 A1) in view of Ragheb et al. (WO 98/36784 A1), Applicants' arguments filed August 27, 2007 have been fully considered but they are not persuasive.

a. The coatings/wrappings are disclosed as either liquid or as sheet-like biopolymer that may be wrapped around the outer surface of the orbital implant (see Abstract; page 13, line 34 to page 14, line 2; page 22, lines 3-10).

b. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

c. In response to Applicants' piecemeal analysis of the references, it has been held that one cannot show nonobviousness by attacking references individually where, as here, the rejections are based on combinations of references. *In re Keller*, 208 USPQ 871 (CCPA 1981).

d. In response to Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. *In re Nomiya*, 184 USPQ 607 (CCPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA 1971).

***Conclusion***

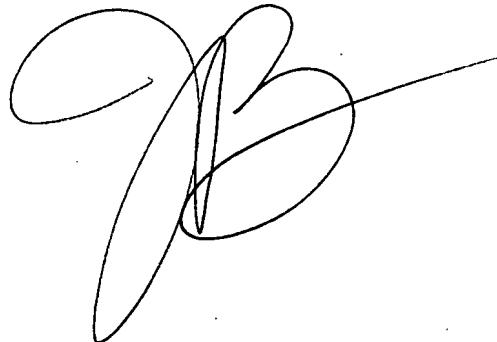
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 2<sup>nd</sup>, 2007

Javier G. Blanco



  
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